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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,994	01/19/2005	Robert J. Levy	RCHP-132US	1713

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EXAMINER	
GILLESPIE, BENJAMIN	
ART UNIT	**PAPER NUMBER**
1796	
MAIL DATE	**DELIVERY MODE**
12/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,994	LEVY ET AL.	
	Examiner	Art Unit	
	Benjamin J. Gillespie	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23 and 31-40* is/are rejected.

7)☒ Claim(s) *24-30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

2. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

3. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-10, 17-23, 31-32, and 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9-20, 27-29 of copending Application No. 11,233,149. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim steroid lipid and cholesterol pendant modified polyurethanes and a process for their production.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, and 11-19, 31, 35 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Levy et al ('011). Levy et al teach modified polyurethane and method for production comprising a lipid substituent pendant group from at least one urethane nitrogen and/or carbon atom, wherein the pendant is present in at least 10 micromoles for every gram of polyurethane, resulting in about 0.5 to 40% of the urethane nitrogens in the backbone of the polyurethane having a lipid substituent pendant (Abstract; col 4 lines 20-25). Furthermore, patentees teach that the modified polyurethane has different lipid substituents pendant from the urethane nitrogens and the resulting polymer exhibits improved chemical degradation resistance (Col 3 lines 35-60; col 7 lines 1-7).

6. Regarding the method of production, Levy et al explain that the polyurethane is reacted with a multifunctional linker reagent consisting of dibromoalkyl and/or bromo-epoxyalkyl compounds, followed by reacting the resulting bromo-modified polyurethane with the lipid substituent (Col 8 lines 37-52; col 9 lines 1-16; col 10 lines 45-67; col 11 lines 1-7). Finally, Levy et al teach the modified polyurethane may be used in cardiovascular implants, angioplasty devices, and cardiac catheters (Col 14 lines 41-42).

7. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Thomas et al ('136). Thomas et al teach modified polyurethane having cholesterol pendant from at least one carbon atom (Col 2 lines 23-30; 45-52).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 2-3, 5-9, 20, 21, 23, 32-34, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al ('011) in view of Leong et al (2002/0045263). Aforementioned, Levy et al teach a phosphonate lipid-modified polyurethane useful in medicine for cardiovascular implants, angioplasty devices, and cardiac catheters, but there is no discussion as to what type of cell the implant is exposed to, specifically endothelial cells or a cholesterol modified lipid substituent. Although there is no specific teaching that the implant of Levy et al is directed towards endothelial cells, it would have been obvious to use the composition in such applications

based on the motivation that patentees direct the invention towards cardiovascular, specifically angioplasty devices, which contact blood vessels.

9. Leong et al teach bioimplantable polymers having urethane and phosphate linkages, wherein the resulting polymer is useful in implants that provide anti-thrombogenic properties (Abstract, paragraphs 9, 56, and 304). In particular, Leong et al teach that when an implant that contains amphiphilic phosphates groups, it is advantageous for the polymer to also contain hydrophobic groups pendant from the polymer backbone, specifically steroid derivatives such as amino-functional cholesterol (Paragraphs 55, 120, and 121).

10. It would have been obvious to one of ordinary skill in the art at the time of invention to include pendant cholesterol groups in the polymer of Levy et al based on the motivation that when phosphonate groups are present in a bioimplant, it is preferred to additionally include said cholesterol groups, as taught by Leong et al.

11. Claims 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al ('011) in view of Smith ('423). As previously discussed, Levy et al renders obvious a lipid-modified polyurethane useful in anti-thrombogensis medical devices that interact with endothelial cells, but there is no discussion of first seeding the implant with endothelial cells prior to implantation. Smith teaches vascular prosthesis having anti-thrombogenic characteristics, and in particular Smith teaches that it is beneficial to first seed endothelial cells on the implant prior to implantation because it provides the implant with improved adhesion when applied to the tissue surface (Col 1 lines 9-22).

12. Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to utilize the teaching of Smith and attach endothelial cells to the bio-implant of Levy

et al based on the motivation that it provides improved adhesion to living tissue in anti-thrombogenic applications.

Response to Arguments

Applicant's arguments filed 9/28/2007 with respect to the rejection of claims 1, and 11-19, 31, 35 and 36 as being anticipated by Levy et al ('011), have been fully considered but they are not persuasive. Applicants argue that polyurethane of Levy et al does not anticipate the claimed invention because the pendant groups do not consist of lipids or lipid based substituents, the examiner disagrees. Lipids, as defined by Hawley's' Condensed Chemical Dictionary, consists of fatty acids, alcohols, sterols, and waxes, wherein waxes are commonly known to consist of long hydrocarbon chains. Column 3 lines 44-65, specifically line 65 of Levy et al, which shows variable "x" is defined as a C_{18} alkylene chain, satisfies the "hydrocarbon chain," limitation.

13. Applicant's arguments filed 9/28/2007 with respect to the rejection of claims 1 and 2 as being anticipated by Thomas et al ('136), have been fully considered but they are not persuasive. Applicants argue that Thomas et al do not anticipate claims 1 and 2 because patentees have failed to teach a polyurethane having pendant lipid substituents, and instead only teach a mixture of polyurethane and cholesterol modified unsaturated compounds. The examiner would like to point out column 3 lines 1-27, which teaches the structure of the cholesterol substituent, and in particular it should be noted that the cholesterol group is attached to an ethylenically unsaturated compound via urethane bond (Col 3 lines 26). Although the single structure listed on column 1 lines 1-3 would only contain one urethane bond, and therefore can not be classified as a "polyurethane," it should be further noted that cholesterol modified unsaturated compounds can

undergo free-radical polymerization and thereby forming a polymer, which contains **multiple** cholesterol groups and urethane linkages.

14. Applicant's arguments filed 9/28/2007 with respect to the rejection of claims 2-3, 5-9, 20, 21, 23, 32-34, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al ('011) in view of Leong et al (2002/0045263), have been fully considered but are not persuasive. Firstly, applicants argue that while the polymer produced by Leong et al contains "some urethane" linkages, it is not a polyurethane. The examiner would like to point out that the language "polyurethane" is not limited to a certain polymer backbone architecture, and instead only limited to the presence of multiple urethane linkages, and therefore contrary to applicants' remarks, the presence of "some urethane" groups satisfies the claim language. What's more, is page 18, Scheme 1, points to a representative polymer repeating unit, and in particular shows the presence of a pendant lipid groups connected to a polymer backbone via urethane bond, wherein the unit is present by n, which is greater than 1. Hence, the classification of Leong et al as a "polyurethane" is adequate because the polymer contains multiple covalently bonded urethane linkages within the polymer structure.

15. Applicants argue that one of ordinary skill in the art would not be motivated to combine the teachings of Levy et al and Leong et al because Levy et al is drawn to polymers containing phosphonates, while Leong et al is drawn to polymers containing polyphosphates, however the determination that a reference is from a nonanalogous art is twofold. First, it is decided if the reference is within the field of the inventor's endeavor, and if it is not, then it must be determined whether the reference is reasonably pertinent to the particular problem with which the inventor was involved. *In re Wood,* 202 USPQ 171, 174; *In re Clay,* 23 USPQ.2d 1058.

16. Based on the test set forth above, although Levy et al and Leong et al are drawn to polymers containing different phosphorous compounds, both teachings satisfy the test for analogous prior art. First Leong et al in Levy et al are both drawn to bio-compatible polyurethanes, and more importantly the teachings of Leong et al are drawn to the enhancement of this property through the inclusion of pendant steroid groups.

Allowable Subject Matter

17. Claims 24-30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin J. Gillespie whose telephone number is 571-272-2472.

The examiner can normally be reached on 8am-5:30pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on 571-272-1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

B. Gillespie

RABON SERGENT
PRIMARY EXAMINER